Supreme Court, U.S.
FILED
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(12)

No. 98-1152

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

JOINT APPENDIX

SETH P. WAXMAN
Solicitor General
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

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for Petitioners

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WILLIAM & CONNOLLY
725 12th Street, N.W.
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for Respondents

PETITION FOR WRIT OF CERTIORARI FILED: JANUARY 19, 1999
CERTIORARI GRANTED: APRIL 26, 1999

b7PP

TABLE OF CONTENTS

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
(GREENSBORO)

Civil No. 95-CV-591

COYNE BEAHM, INC., BROWN & WILLIAMSON TOBACCO CORPORATION, LIGGETT GROUP, INC., LORILLARD TOBACCO COMPANY, PHILIP MORRIS, INCORPORATED, R. J. REYNOLDS TOBACCO COMPANY, PLAINTIFFS

v.

UNITED STATES FOOD & DRUG ADMINISTRATION, DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS

DOCKET ENTRIES

DATE	DOCKET NUMBERS	PROCEEDINGS
		* * * * *
8/23/96	27	MOTION by COYNE BEAHM, INC., BROWN & WILLIAMSON, LIGGETT GROUP, INC., LORILLARD TOBACCO CO, MORRIS, PHILIP, INC., REYNOLDS, R. J., TOB for Leave to File Second Amended Complaint w/proposed Second Amended Com

DATE	DOCKET NUMBERS	PROCEEDINGS
		plaint attached. (ww) [Entry date 08/26/96]
		* * * * *
10/1/96	34	ANSWER by US FOOD & DRUG ADMIN, DAVID A. KESSLER to second amended complaint (ww) [Entry date 10/02/96]
		* * * * *
10/15/96	36	MOTION FOR SUMMARY JUDGMENT by plaintiff COYNE BEAHM, INC., plaintiff BROWN & WILLIAMSON, plaintiff LORILLARD TOBACCO CO, plaintiff MORRIS, PHILIP, INC., plaintiff REYNOLDS, R. J., TOB (rh)
		* * * * *
2/10/97	—	Motion hearing held before Jd. Osteen, G'boro. Beck Rptr. re: [36-1] motion FOR SUMMARY JUDGMENT by REYNOLDS, R. J., TOB, MORRIS, PHILIP, INC., LORILLARD TOBACCO CO, BROWN

DATE	DOCKET NUMBERS	PROCEEDINGS
		& WILLIAMSON, COYNE BEAHM, INC., Ct will enter findings in 5-10 weeks. (jm) [Entry date 02/11/97]
		* * * * *
4/25/97	70	MEMORANDUM OPINION (signed by Judge William L. Osteen Sr.) Re: [36-1] motion for summary judgment. Ccs. to counsel. (cg)
4/25/97	71	ORDER (signed by Judge William L. Osteen Sr.) [36-1] motion for summary judgment is granted as to the regulations' restrictions on the promotion and advertising of tobacco products and denied as to the Regulations access restrictions and labeling requirements. An immediate appeal from this order may materially advance the ultimate termination of the litigation. Therefore the court certifies this order for an interlocutory appeal purs. to 28 USC 1292(b). The Regula

DATE	DOCKET NUMBERS	PROCEEDINGS
		tions heretofore implemented prohibiting the sale of tobacco products to minors shall remain in full force and effect pending appeal by pltfs. The Food and Drug Administration shall not implement any of the additional Regulations set for implementation on 8/28/97, pending further orders by the court. Nothing set forth in this order concerning the time of implemetation of the Regulations shall prohibit either side from presenting motions to the court for a reconsideration as to the implementation of the regulations pending appeal. Further ordered that absent a timely appeal or absent permission of the Court of Appeals for the Fourth Circuit to proceed with an interlocutory appeal, this matter shall proceed for ultimate disposition by the court. Ccs. to counsel. (cg) [Edit date 04/25/97]

DATE	DOCKET NUMBERS	PROCEEDINGS
5/2/97	72	NOTICE OF APPEAL from order entered 4/25/97 to USCA 4th Circuit by US FOOD & DRUG ADMIN, DAVID A. KESSLER. (rh)

* * * * *

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
(GREENSBORO)

Civil No. 95-CV-593

AMERICAN ADVERTISING FEDERATION,
AMERICAN ASSOCIATION OF ADVERTISING AGENCIES,
ASSOCIATION OF NATIONAL ADVERTISERS, INC.,
MAGAZINE PUBLISHERS OF AMERICA,
OUTDOOR ADVERTISING ASSOCIATION OF AMERICA,
POINT OF PURCHASE ADVERTISING INSTITUTE,
PLAINTIFFS

v.

DAVID A. KESSLER, M.D., COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, UNITED STATES
UNITED STATES FOOD & DRUG ADMINISTRATION,
DEFENDANTS

DOCKET ENTRIES

DATE	DOCKET NUMBERS	PROCEEDINGS
		* * * * *
9/16/96	39	SECOND AMENDED COMPLAINT by AMERICAN ADVERTISING, AMERICAN ASSOCIATION, ASSN. OF NATL. ADVT., MAGAZINE PUBLISHERS, OUTDOOR AD

DATE	DOCKET NUMBERS	PROCEEDINGS
		VERTISING, POINT OF PURCHASE amending [1-1] complaint (kd) [Entry date 09/19/96]
		* * * * *
10/1/96	41	ANSWER by DAVID A. KESSLER, US FOOD & DRUG ADMIN to second amended complaint. (kd) [Entry date 10/02/96]
		* * * * *
10/15/96	45	MOTION FOR SUMMARY JUDGMENT by plaintiff AMERICAN ADVERTISING, plaintiff AMERICAN ASSOCIATION, plaintiff ASSN. OF NATL. ADVT., plaintiff MAGAZINE PUBLISHERS, plaintiff OUTDOOR ADVERTISING, plaintiff POINT OF PURCHASE (kd) [Entry date 10/16/96]
		* * * * *
2/10/97	—	Motion hearing held before Jd. Osteen, G'boro. Beck Rptr.

DATE	DOCKET NUMBERS	PROCEEDINGS
		re: [45-1] motion FOR SUMMARY JUDGMENT by plaintiffs. Ct will enter findings in 5-10 weeks. (jm) [Entry date 02/11/97]
		* * * * *
4/25/97	66	MEMORANDUM OPINION (copy - original filed in 2:95CV591) (signed by Judge William L. Osteen Sr.) [45-1] motion for summary judgment. Ccs. to counsel. (cg)
4/25/97	67	ORDER (copy - original filed in 2:95CV591) (signed by Judge William L. Osteen Sr.) [45-1] motion for summary judgment is granted as to the Regulations' restrictions on the promotion and advertising of tobacco products and denied as to the Regulations access restrictions and labeling requirements. An immediate from this order may materially advance the ultimate termination of the litigation. Therefore, the court

DATE	DOCKET NUMBERS	PROCEEDINGS
		certifies this order for an interlocutory appeal purs. to 28 USC 1292(b). The Regulations heretofore implemented prohibiting the sale of tobacco products to minors shall remain in full force and effect pending appeal by pltfs. The Food and Drug Administration shall not implement any of the additional Regulations set for implementation on 8/28/97, pending further orders by the court. Nothing set forth in this order concerning the time of implementation of the Regulations shall prohibit either side from presenting motions to the court for a reconsideration as to the implementation of the Regulations pending appeal. Further ordered that absent a timely appeal or absent permission of the Court of Appeals for the Fourth Circuit to proceed with an interlocutory appeal, this matter shall proceed for ultimate disposition by the court. Ccs. to counsel. (cg) [Edit date 04/25/97]

DATE	DOCKET NUMBERS	PROCEEDINGS
5/2/97	68	NOTICE OF APPEAL from order entered 4/25/97 (copy-original filed in 2:95CV591) to USCA 4th Circuit by DAVID A. KESSLER, US FOOD & DRUG ADMIN (rh)

* * * * *

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
(WINSTON-SALEM)

Civil No. 95-CV-665

UNITED STATES TOBACCO COMPANY, BROWN & WILLIAMSON TOBACCO CORPORATION, CONWOOD COMPANY, L.P., NATIONAL TOBACCO COMPANY, L.P., THE PINKERTON TOBACCO COMPANY, SWISHER INTERNATIONAL, INC., CENTRAL CAROLINA GROCERS, INC., J. T. DAVENPORT, INC., N. C. TOBACCO DISTRIBUTORS COMMITTEE, INC., PLAINTIFFS

v.

UNITED STATES FOOD & DRUG ADMINISTRATION, DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS

DOCKET ENTRIES

DATE	DOCKET NUMBERS	PROCEEDINGS
		* * * * *
8/23/96	21	FIRST AMENDED COMPLAINT by ALL PLAINTIFFS amending [1-1] complaint (cmh) [Entry date 08/26/96]
		* * * * *

DATE	DOCKET NUMBERS	PROCEEDINGS
10/1/96	25	ANSWER by US FOOD & DRUG ADMIN, DAVID A. KESSLER to amended complaint (cmh) [Entry date 10/02/96]
		* * * * *
10/15/96	27	MOTION For Summary Judgment invalidating and permanently enjoining enforcement of the FDA Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to protect Children and Adolescents by ALL PLAINTIFFS. (cmh)
		* * * * *
2/10/97	—	Motion hearing held before Jd. Osteen, G'boro. Beck Rptr. re: [27-1] motion For Summary Judgment invalidating and permanently enjoining enforcement of the FDA Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to protect Children and Adolescents by ALL PLAIN-TIFFS. Ct will enter findings in 5-10 weeks. (jm) [Entry date 02/11/97]

DATE	DOCKET NUMBERS	PROCEEDINGS
		* * * * *
4/25/97	60	MEMORANDUM OPINION (copy - original filed in 2:95CV591) (signed by Judge William L. Osteen Sr.) Re: [27-1] motion for summary judgment. Ccs. to counsel. (cg)
4/25/97	61	ORDER (copy - original filed in 2:95CV591) (signed by Judge William L. Osteen Sr.) [27-1] motion for summary judgment is granted as to the Regulations restrictions on the promotion and advertising of tobacco products and denied as to the Regulations Access restrictions and labeling requirements. An immediate appeal from this order may materially advance the ultimate termination of the litigation. Therefore, the court certifies this order for an interlocutory appeal purs. to

DATE	DOCKET NUMBERS	PROCEEDINGS
		28 USC 1292(b). The Regulations heretofore implemented prohibiting the sale of tobacco products to minors shall remain in full force and effect pending appeal by pltfs. The Food and Drug Administration shall not implement any of the additional Regulations set for implementation on 8/28/97, pending further orders by the court. Nothing set forth in this order concerning the time of implementation of the Regulations shall prohibit either side from presenting motions to the court for a reconsideration as to the implementaion of the regulations pending appeal. Further ordered that adsent a timely appeal or absent permission of the Court of Appeals for the Fourth Circuit to proceed with an interlocutory appeal, this matter shall proceed for ultimate disposition by the court. Ccs. to counsel. (cg)

DATE	DOCKET NUMBERS	PROCEEDINGS
5/2/97	62	NOTICE OF APPEAL from order entered 4/25/97 (copy-original filed in 2:95CV591) to USCA 4th Circuit by US FOOD & DRUG ADMIN, DAVID A. KESSLER (rh)

* * * * *

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
(GREENSBORO)

Civil No. 95-CV-706

NATIONAL ASSOCIATION OF CONVENIENCE STORES, ACME RETAIL, INC., PLAINTIFFS

v.

DAVID A. KESSLER, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION, UNITED STATES FOOD & DRUG ADMINISTRATION, DEFENDANTS

DOCKET ENTRIES

DATE	DOCKET NUMBERS	PROCEEDINGS
		* * * * *
8/30/96	13	FIRST AMENDED COMPLAINT by NATL. ASSN. CONV., ACME RETAIL, INC. amending [1-1] complaint. (cmh)
		* * * * *
10/1/96	17	ANSWER by DAVID A. KESSLER, US FOOD & DRUG ADMIN to amended complaint (cmh) [Entry date 10/02/96]

DATE	DOCKET NUMBERS	PROCEEDINGS
		* * * * *
10/15/96	20	MOTION For Summary Judgment invalidating and permanently enjoining enforcement of the FDA Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco by plaintiff NATL. ASSN. CONV., plaintiff ACME RETAIL, INC. (cmh) [Entry date 10/16/96]
		* * * * *
2/10/97	—	Motion hearing held before Jd. Osteen, G'boro. Beck Rptr. re: [20-1] motion For Summary Judgment invalidating and permanently enjoining enforcement of the FDA Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco by ACME RETAIL, INC., NATL. ASSN. CONV. Ct will enter findings in 5-10 weeks. (jm) [Entry date 02/11/97]
		* * * * *

DATE	DOCKET NUMBERS	PROCEEDINGS
4/25/97	52	MEMORANDUM OPINION (copy - original filed in 2:95CV591) (signed by Judge William L. Osteen Sr.) Re: [20-1] motion for summary judgment. Ccs. to counsel. (cg)
4/25/97	53	ORDER (copy - original filed in 2:95CV591) (signed by William L. Osteen Sr.) [20-1] motion for summary judgment is granted as to the Regulations restrictions on the promotion and advertising of tobacco products and denied as to the Regulations access restrictions and labeling requirements. An immediate appeal from this order may materially advance the ultimate termination of the litigation. Therefore, the court certifies this order for an interlocutory appeal purs. to 28 USC 1292(b). The Regulations heretofore implemented prohibiting the sale of tobacco products to minors shall remain in full force and effect

DATE	DOCKET NUMBERS	PROCEEDINGS
		pending appeal by pltfs. The Food and Drug Administration shall not implement any of the additional Regulations set for implementation on 8/28/97, pending further orders by the court. Nothing set forth in this order concerning the time of implementation of the Regulations shall prohibit either side from presenting motions to the court for a reconsideration as to the implementation of the regulations pending appeal. Further ordered that absent a timely appeal or absent permission of the Court of Appeals for the Fourth Circuit to proceed with an interlocutory appeal, this matter shall proceed for ultimate disposition by the court. Ccs. to counsel. (cg)

DATE	DOCKET NUMBERS	PROCEEDINGS
5/2/97	54	NOTICE OF APPEAL from order entered 4/25/97 (copy-original filed in 2:95CV591) to USCA 4th Circuit by DAVID A. KESSLER, US FOOD & DRUG ADMIN (rh)

* * * * *

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 97-1581

COYNE BEAHM, INCORPORATED, BROWN & WILLIAMSON TOBACCO CORPORATION, PHILIP MORRIS, INCORPORATED, R. J. REYNOLDS TOBACCO COMPANY, NATIONAL ASSOCIATION OF CONVENIENCE STORES, ACME RETAIL INCORPORATED, UNITED STATES TOBACCO COMPANY, CONWOOD COMPANY, L.P., NATIONAL TOBACCO COMPANY, L.P., PINKERTON TOBACCO COMPANY,
SWISHER INTERNATIONAL, INCORPORATED, CENTRAL CAROLINA GROCERS, INCORPORATED, J. T. DAVENPORT, INCORPORATED, NORTH CAROLINA TOBACCO DISTRIBUTORS COMMITTEE, INCORPORATED, THE AMERICAN ADVERTISING FEDERATION, AMERICAN ASSOCIATION OF ADVERTISING AGENCIES, ASSOCIATION OF NATIONAL ADVERTISERS, INCORPORATED, MAGAZINE PUBLISHERS OF AMERICA, THE OUTDOOR ADVERTISING ASSOCIATION OF AMERICA, INCORPORATED, POINT OF PURCHASE ADVERTISING INSTITUTE, LORILLARD TOBACCO COMPANY, PLAINTIFFS-APPELLEES
AND
LIGGETT GROUP, INCORPORATED, PLAINTIFF

v.

FOOD & DRUG ADMINISTRATION, DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS-APPELLANTS

DOCKET ENTRIES

DATE	PROCEEDINGS
	* * * * *
8/11/97	Oral argument heard. Courtroom Deputy: Richard Sewell, Joseph Coleman, Diane Burke. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (psc) [97-1581 97-1604 97-1605 97-1606 97-1614]
4/16/98	COURT ORDER filed for reargument of appeal [2754116-1] Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
	* * * * *
6/9/98	Oral argument heard. Courtroom Deputy: JLC, DHB, RHS. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (rhs) [97-1581 97-1604 97-1605 97-1606 97-1614]
	* * * * *
8/14/98	Published, authored opinion filed. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
8/14/98	Judgment order filed. Decision: REVERSED. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]

DATE	PROCEEDINGS
9/25/98	Petition filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604, Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessle in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 for rehearing. Number copies filed: 20 [2851942-1]., for suggestion for rehearing in banc. Number of copies filed: 20 [2851942-2]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
	* * * * *
11/10/98	PUBLISHED COURT ORDER filed denying motion for rehearing [2851942-1] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614, denying motion for suggestion for reh in banc [2851942-2] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
11/16/98	Motion filed by Appellee FDA, et al in 97-1604, Appellant FDA, et al in 97-1581, Appellee FDA, et al. in 97-1605, Appellant FDA, et al. in 97-1606, Appellee FDA, et al. in 97-1614 to stay the mandate

DATE	PROCEEDINGS
	[2882616-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
11/18/98	COURT ORDER filed granting motion to stay mandate [2882616-1] until for a period of 30 days from the date of the filing of this order pending the filing of a petition for certiorari by the government. Judge Hall dissented. 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
12/14/98	Motion filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604, Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 to stay the mandate [898734-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]

DATE	PROCEEDINGS
12/17/98	COURT ORDER filed granting motion to stay mandate [2898734-1] until January 18, 1999 in 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]

* * * * *

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

No. 97-1604

BROWN & WILLIAMSON TOBACCO CORPORATION, LORILLARD TOBACCO COMPANY, PHILIP MORRIS, INCORPORATED, R. J. REYNOLDS TOBACCO COMPANY, PLAINTIFFS-APPELLANTS

AND

COYNE BEAHM, INCORPORATED, LIGGETT GROUP, INCORPORATED, PLAINTIFFS

v.

FOOD & DRUG ADMINISTRATION, DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS-APPELLEES

DOCKET ENTRIES

DATE	PROCEEDINGS
	* * * * *
8/11/97	Oral argument heard. Courtroom Deputy: Richard Sewell, Joseph Coleman, Diane Burke. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (psc) [97-1581 97-1604 97-1605 97-1606 97-1614]

DATE	PROCEEDINGS
4/16/98	COURT ORDER filed for reargument of appeal [2754116-1] Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
	* * * * *
6/9/98	Oral argument heard. Courtroom Deputy: JLC, DHB, RHS. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (rhs) [97-1581 97-1604 97-1605 97-1606 97-1614]
	* * * * *
8/14/98	Published, authored opinion filed. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
8/14/98	Judgment order filed. Decision: REVERSED. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
9/25/98	Petition filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604,

DATE	PROCEEDINGS
	Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 for rehearing. Number copies filed: 20 [2851942-1]., for suggestion for rehearing in banc. Number of copies filed: 20 [2851942-2]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
	* * * * *
11/10/98	PUBLISHED COURT ORDER filed denying motion for rehearing [2851942-1] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614, denying motion for suggestion for reh in banc [2851942-2] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
11/16/98	Motion filed by Appellee FDA, et al in 97-1604, Appellant FDA, et al in 97-1581, Appellee FDA, et al. in 97-1605, Appellant FDA, et al. in 97-1606, Appellee FDA, et al. in 97-1614 to stay the mandate [2882616-1].

DATE	PROCEEDINGS
	[97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
11/18/98	COURT ORDER filed granting motion to stay mandate [2882616-1] until for a period of 30 days from the date of the filing of this order pending the filing of a petition for certiorari by the government. Judge Hall dissented. 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
12/14/98	Motion filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604, Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 to stay the mandate [2898734-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
12/17/98	COURT ORDER filed granting motion to stay mandate [2898734-1] until January 18,

DATE	PROCEEDINGS
	1999 in 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
	* * * * *

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 97-1605

UNITED STATES TOBACCO COMPANY, BROWN & WILLIAMSON TOBACCO CORPORATION, CONWOOD COMPANY, L.P., NATIONAL TOBACCO COMPANY, L.P., PINKERTON TOBACCO COMPANY, SWISHER INTERNATIONAL, INCORPORATED, CENTRAL CAROLINA GROCERS, INCORPORATED, J. T. DAVENPORT, INCORPORATED, NORTH CAROLINA TOBACCO DISTRIBUTORS COMMITTEE, INCORPORATED,
PLAINTIFFS-APPELLANTS

v.

FOOD & DRUG ADMINISTRATION, DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS,
DEFENDANTS-APPELLEES

DOCKET ENTRIES

DATE	PROCEEDINGS
	* * * * *
8/11/97	Oral argument heard. Courtroom Deputy: Richard Sewell, Joseph Coleman, Diane Burke. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (psc) [97-1581 97-1604 97-1605 97-1606 97-1614]

4/16/98	COURT ORDER filed for reargument of appeal [2754116-1] Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
	* * * * *
6/9/98	Oral argument heard. Courtroom Deputy: JLC, DHB, RHS. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (rhs) [97-1581 97-1604 97-1605 97-1606 97-1614]
	* * * * *
8/14/98	Published, authored opinion filed. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
8/14/98	Judgment order filed. Decision: REVERSED. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
9/25/98	Petition filed by Appellee FDA in 97-1604, Appellee David A. Kessler in 97-1604, Appellant FDA in 97-1581, Appellant David A. Kessler in 97-1581, Appellee FDA in 97-1605, Appellee David A. Kessler in 97-1605, Appellant FDA in 97-1606, Appellant David A. Kessler in 97-1606, Appellee David A. Kessler in 97-1614, Appellee FDA in 97-1614 for rehearing. Number copies filed: 20 [2851942-1]., for

DATE	PROCEEDINGS
	suggestion for rehearing in banc. Number of copies filed: 20 [2851942-2]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
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11/10/98	PUBLISHED COURT ORDER filed denying motion for rehearing [2851942-1] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614, denying motion for suggestion for reh in banc [2851942-2] in 97-1614, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
11/16/98	Motion filed by Appellee FDA, et al in 97-1604, Appellant FDA, et al in 97-1581, Appellee FDA, et al. in 97-1605, Appellant FDA, et al. in 97-1606, Appellee FDA, et al. in 97-1614 to stay the mandate [2882616-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
11/18/98	COURT ORDER filed granting motion to stay mandate [2882616-1] until for a period of 30 days from the date of the filing of this order pending the filing of a petition for certiorari by the government.

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	Judge Hall dissented. 97-1604, 97-1581, 97-1605, 97-1606, 97-1614 Copies to all counsel. [97-1604, 97-1581, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
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UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 97-1606

COYNE BEAHM, INCORPORATED, BROWN & WILLIAMSON TOBACCO CORPORATION, LORILLARD TOBACCO COMPANY, PHILIP MORRIS, INCORPORATED, R. J. REYNOLDS TOBACCO COMPANY, UNITED STATES TOBACCO COMPANY, CONWOOD COMPANY, L.P., NATIONAL TOBACCO COMPANY, L.P., PINKERTON TOBACCO COMPANY, SWISHER INTERNATIONAL, INCORPORATED, CENTRAL CAROLINA GROCERS, INCORPORATED, J. T. DAVENPORT, INCORPORATED, NORTH CAROLINA TOBACCO DISTRIBUTORS COMMITTEE, INCORPORATED, THE AMERICAN ADVERTISING FEDERATION, AMERICAN ASSOCIATION OF ADVERTISING AGENCIES, ASSOCIATION OF NATIONAL ADVERTISERS, INCORPORATED, MAGAZINE PUBLISHERS OF AMERICA, THE OUTDOOR ADVERTISING ASSOCIATION OF AMERICA, INCORPORATED, POINT OF PURCHASE ADVERTISING INSTITUTE, NATIONAL ASSOCIATION OF CONVENIENCE STORES, ACME RETAIL, INCORPORATED, LIGGETT GROUP, INCORPORATED, PLAINTIFFS-APPELLEES

v.

FOOD & DRUG ADMINISTRATION, DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS-APPELLANTS

DOCKET ENTRIES

DATE	PROCEEDINGS
	* * * * *
8/11/97	Oral argument heard. Courtroom Deputy: Richard Sewell, Joseph Coleman, Diane Burke. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (psc) [97-1581 97-1604 97-1605 97-1606 97-1614]
4/16/98	COURT ORDER filed for reargument of appeal [2754116-1] Copies to all counsel. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
	* * * * *
6/9/98	Oral argument heard. Courtroom Deputy: JLC, DHB, RHS. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (rhs) [97-1581 97-1604 97-1605 97-1606 97-1614]
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8/14/98	Published, authored opinion filed. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]
8/14/98	Judgment order filed. Decision: REVERSED. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (mst) [97-1581 97-1604 97-1605 97-1606 97-1614]

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DATE	PROCEEDINGS
	in 97-1614 to stay the mandate [2882616-1]. [97-1604, 97-1581, 97-1605, 97-1606, 97-1614] (dhb) [97-1581 97-1604 97-1605 97-1606 97-1614]
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UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 97-1614

NATIONAL ASSOCIATION OF CONVENIENCE STORES,
ACME RETAIL, INCORPORATED,
PLAINTIFFS-APPELLANTS

v.

DAVID A. KESSLER, COMMISSIONER OF THE
FOOD & DRUG ADMINISTRATION,
FOOD & DRUG ADMINISTRATION,
DEFENDANTS-APPELLEES

DOCKET ENTRIES

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[SEAL OMITTED]

Department of Health Education and Welfare
Public Health Service
Food and Drug Administration
Rockville, Maryland 20452

December 05, 1997

Mr. John F. Banzhaf, III
Executive Director and General Counsel
Action on Smoking and Health
2000 H Street, N.W.
Washington, D.C. 20006

Dear Mr. Banzhaf:

This is in reply to your petition dated May 26, 1977, requesting that the Food and Drug Administration (FDA) take the following action:

1. Recognition of the FDA's jurisdiction over cigarettes containing nicotine (or nicotine separately) as a "drug" or, in the alternative, as a "device" pursuant to 21 U.S.C. 321.

2. Regulation of cigarettes no less strictly than saccharin.

3. Restriction of the sale of cigarettes containing nicotine to pharmacies pursuant to 21 U.S.C. 353.

At a meeting on July 28, 1977, between you and Dr. Luther Terry, representing the petitioner, and several

employees of FDA and me, the petition was discussed. You stated that the petitioners planned to submit additional material supplementing the petition, and that the supplement would be filed with FDA in September 1977. This supplement was submitted on November 15, 1977.

The petition submitted on May 26, 1977, and the supplemental memorandum of November 15, 1977, have been reviewed. Your requests that FDA assert jurisdiction over cigarettes containing nicotine (or nicotine separately) as a drug under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 *et seq.*, and that FDA restrict the sale of cigarettes to pharmacies under 21 U.S.C. § 353 are denied. However, FDA can assert jurisdiction over cigarettes containing nicotine (or nicotine separately) as a drug when a jurisdictional basis for doing so exists, e.g., health claims made by the vendors *Fairfax Cigarettes, infra* and *Trim Reducing Cigarettes, infra.*

The request in your petition that FDA regulate the sale of cigarettes no less strictly than saccharin is withdrawn in your supplemental memorandum; therefore, no response to this request is necessary. The request in your petition that FDA assert jurisdiction over cigarettes as a device pursuant to 21 U.S.C. § 321 will be responded to by FDA in connection with your planned separate petition, on FDA regulation of cigarette filters as devices, to which you refer on page five of your supplemental memorandum. The Agency will respond to the separate petition and to your request for FDA regulation of cigarettes as a device within 180 days of the receipt of your separate petition, (21 C.F.R. § 10.30(e)).

The petitioners state in the supplemental memorandum that the serious health hazard posed by the extensive variety of additives in cigarettes and the clear absence of regulatory authority in any other Federal Agency are compelling reasons for the FDA to exercise its jurisdiction and strong evidence that such jurisdiction has not been precluded. Petitioners themselves answer these contentions by admitting at pages 9 and 10 of the supplemental memorandum that no law controls the additives to cigarettes.

> Insofar as ASH is aware, there is no law which would prohibit cigarette manufacturers from adding to their products additional additives or tobacco substitutes, whether these contain natural products like lettuce leaves, chemical compounds such as Cytrel or NSM, or even known or suspected carcinogens. Moreover, no law appears to require the manufacturers to report such changes in the compositions of their products either to the consumers or to any federal or state agency.

FDA cannot assert jurisdiction over additives in cigarettes unless FDA has statutory jurisdiction over the cigarettes. FDA has asserted jurisdiction over cigarettes when a jurisdictional basis for so doing has existed (*Fairfax Cigarettes, infra* and *Trim Reducing Cigarettes, infra*).

Two court decisions in the 1950's demonstrate that FDA has regulated cigarettes when health claims were made by the manufacturers. In *United States* v. *46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D. N.J., 1953), the Court held that the cigarettes were a drug within the meaning of the

Federal Food, Drug, and Cosmetic Act (the Act) because the advertising suggested that the cigarettes were effective in preventing respiratory and other diseases. These drug claims brought the cigarettes within the term "drug" as used in the Act. The other case, *United States* v. *354 Bulk Cartons Trim Reducing Cigarettes*, 178 F. Supp. 847 (D. N.J., 1959), involved cigarettes containing tartaric acid, which were represented to be effective for combatting [*sic*] obesity. On the basis of the weight-reducing claims made on the packages and in other advertising, the Court held that these cigarettes constituted a drug.

One decision that has been discussed frequently in connection with the conclusion that cigarettes are not a drug under the Act is *Federal Trade Commission* v. *Liggett & Myers Tobacco Co.*, 108 F. Supp. 573 (S.D. N.Y., 1952), *affirmed* 203 F.2d 955 (2nd Cir., 1953). The Court construed the definition of the term "drug" in the Federal Trade Commission Act–which is the same definition as in the Federal Food, Drug, and Cosmetic Act–not to include cigarettes. At page 577, the Court stated: "The legislative history, such as it is, coupled with indications of contemporaneous administrative interpretation leads me to the conclusion that Congress, had the matter been considered, would not have intended cigarettes to be included as an article 'intended to affect the functions of the body of man' or in any other definition of 'drug'."

No court has held that cigarettes are a drug under the Act. The interpretation of the Act by FDA consistently has been that cigarettes are not a drug unless health claims are made by the vendors.

Your petition focused the argument that cigarettes are a drug under the Act of the statutory definition of the term "drug" in 21 U.S.C. 321(g)(1)(C):

> articles (other than food) intended to affect the structure or any function of the body of man or other animals. . .

The meaning of the word "intended" in 21 U.S.C. § 321 was construed in a 1977 appellate court decision, *National Nutritional Foods Ass'n.* v. *Mathews*, 557 F.2d 325 (2nd Cir., 1977). The Court stated: "The vendors' intent in selling the product to the public is the key element in this statutory definition" (557 F.2d at 333). The court stated that the Commissioner of Food and Drugs had acted arbitrarily and capriciously in proposing to regulate high potency Vitamin A and D preparationa [*sic*] as drugs under the Act.

> The determination that an article is properly regulated as a drug, however, is not left to the Commissioner's unbridled discretion to act to protect the public health but must be in accordance with the statutory definition. Toxicity is not included as an element in the statutory definition of a drug. It is relevant as a factor supporting the Commissioner's classification under § 201(g)(1)(B), but only to the extent that it constitutes objective evidence of therapeutic intent. 557 F.2d at 334-335.

The petitioners have presented no evidence that manufacturers or vendors of cigarettes represent that the cigarettes are "intended to affect the structure or any function of the body of man. . ." 21 U.S.C. § 321(g)(1)(C). Statements by the petitioners and citations in the petition that cigarettes are used by smokers to affect the structure or any functions of their bodies

are not evidence of such intent by the manufacturers or vendors of cigarettes, as required under the provisions of 21 U.S.C. § 321(g)(1)(C) (see *National Nutritional Foods Ass'n., supra*, at 355).

The petitioners cite *United States* v. *An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784 (1968), for a liberal construction of the Act consistent with its overriding purpose to protect the public health. In evaluating this contention, the court in *National Nutritional Foods Ass'n., supra* at 336, stated:

> The drug definition is to be given a liberal interpretation in light of the remedial purposes of the legislation, *see, United States* v. *An Article of Drug . . . Bacto-Unidisk* (citation omitted), but when an FDA determination that an article is a "drug" is so directly in conflict with the statutory definition, it must be invalidated as arbitrary and capricious and not in accordance with law.

Therefore, your request that FDA regulate cigarettes as a drug under the Act is denied. Based upon this conclusion, your requests that FDA restrict the sale of cigarettes to pharmacies pursuant to the Act and that FDA assert its jurisdiction over additives in cigarettes are also denied. Upon receipt of a separate petition requesting FDA regulation of cigarette filters as devices, the Agency will respond to that additional request.

Sincerely yours,

/s/ DONALD KENNEDY
DONALD KENNEDY
Commissioner of Food and Drugs

[SEAL OMITTED]

Department of Health Education and Welfare
Public Health Service
Food and Drug Administration
Rockville, Maryland 20857

November 25, 1980

John F. Banzhaf, III
Peter N. Georgiades
Action on Smoking and Health
2000 H St., NW
Washington, DC 20006

Re: Docket Nos. 77P-0185
78P-0338/CP

Dear Messrs. Banzhaf and Georgiades:

This replies to the pending requests in the petitions filed by Action on Smoking and Health (ASH), et al., on May 26, 1977 (Petition No. 1) and on October 2, 1978 (Petition No. 2), and supplements to them. Your petitions request the Food and Drug Administration (FDA) to recognize its jurisdiction over the following as medical devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h):

(1) Cigarettes containing nicotine (Petition No. 1);

(2) Cigarette filters, which you describe as basically "the 'detached' filter, which is purchased separately from the cigarettes and is installed by the smoker on the end of the cigarette" and "the 'attached' filter [which] . . . is an integral part of many brands of cigarette" (Petition No. 2, pp. 5-6).

ASH also requests that FDA commence rulemaking to determine an appropriate scheme for regulating cigarettes and cigarette filters as medical devices.

We will respond first to Petition No. 1 concerning cigarettes containing nicotine and next to Petition No. 2 concerning cigarette filters. Because we agree with your statement (Petition No. 2, p. 6) that "it is conceptually easier to discuss detached and attached filters separately," we will respond separately with respect to "attached" and "detached" filters. Finally, we will respond to your request that FDA commence rulemaking to determine an appropriate regulatory scheme. In preparing our response, we have considered the comments and other documents filed with the respective petitions in the Dockets Management Branch (formerly the Hearing Clerk's office) as well as the petitions themselves.

I. Cigarettes Containing Nicotine

For the reasons discussed below, we are denying the pending requests in Petition No. 1 concerning cigarettes containing nicotine as "devices."

Petition No. 1 (p. 31) sets forth your view that "cigarettes containing nicotine could be regulated either as 'drugs' or as 'devices.'" As you know, on December 5, 1977, we denied your request to recognize jurisdiction over cigarettes containing nicotine under the definition of "drug" in section 201(g) of the Act, 21 U.S.C. 321(g). That denial has been extensively briefed, both before the District Court and the United States Court of Appeals for the District of Columbia, where the matter is presently pending. (*ASH v. Harris*, D.C. Cir., No. 79-1397). The "drug" issue will not be further discussed here.

Petition No. 1 broadly requests (e.g., p. 31) that FDA recognize jurisdiction over cigarettes as a "device" under section 201(h) of the Act, but does not specifically assert or present evidence that cigarettes are a "device" under the provisions of clauses (1) or (2) of section 201(h), 21 U.S.C. 321(h)(1) or (2). We find that cigarettes are not recognized in the official National Formulary or the United States Pharmacopeia, or any supplement to them, and that there is no evidence in the petition that cigarettes are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. Accordingly, insofar as Petition No. 1 may be deemed to request that FDA regulate cigarettes containing nicotine as a "device" under section 201(h)(1) or (2) of the Act, we deny your request.

With respect to the application of section 201(h)(3) of the Act, 21 U.S.C. 321(h)(3), Petition No. 1 asserts that when the definition of "device" was enacted in 1938 it was intended to expand the agency's jurisdiction beyond that provided over "drugs" (p. 30) and that the

"device" category is a far broader category than that of "drug" (p. 31).

The legislative history of the development of the definitions of "drug" and "device" as enacted in 1938 is discussed at length by the Supreme Court in *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 794-800 (1969), where the Court treats the interpretation of the "intended use" portion of both definitions as presenting the same issues when considered under either section 201(g) or then 201(h). The language of current section 201(h)(3) was contained in the "device" definition prior to the "Medical Device Amendments of 1976," (the amendments), Pub. L. 94-295. Petition No. 1 fails to establish that there are any differences between the scope of "device" jurisdiction before and after the amendments that are pertinent to determining whether cigarettes containing nicotine are "intended to affect the structure or any function of the body of man" within the meaning of section 201(h)(3) of the Act. Also, there is no suggestion in the legislative history of the amendments that Congress intended that portion of the definition to be interpreted in a different manner than it had been previously or than the identical language found in the "drug" definition in section 201(g)(1)(C) of the Act, 21 U.S.C. 321(g)(1)(C).

The report on the amendments by the House Committee on Interstate and Foreign Commerce (H.R. Rep. No. 94-853, 94th Cong., 2d Sess., p. 14 (1976)) notes that the purpose of amending the definition is "to draw a clear distinction between a 'device' and a 'drug';" that the definition generally retains provisions of existing law concerning intended use; that those characteristics are also used in the definition of a "drug" in section

201(g) of the Act; but, adds the chemical action and metabolism modification to "remov[e] the gray area that exists under present definitions."

Specifically, there is no evidence in the legislative history that Congress intended to include cigarettes within the definition of "device" nor does the legislative history contain any discussion of a possibility that cigarettes were "devices" within the prior definition.

The amendments were thoroughly considered, and the legislative history discusses the types of products intended to be regulated and the types of health hazards with respect to which the amendments were intended to provide authority. Cigarettes are not mentioned even though Congress was aware of the considerable public discussion of the health hazards of cigarette smoking. It is, therefore, not reasonable to consider cigarettes as "devices" when there was no discussion in the legislative history of congressional intent to provide jurisdiction over cigarettes or to provide authority suitable to the regulation of cigarettes.

FDA has long believed and has repeatedly advised inquirers that cigarettes as customarily marketed are intended solely for smoking purposes or smoking pleasure and are not within FDA's jurisdiction under the Act. Indeed, this interpretation is involved in the pending appeal in *ASH* v. *Harris*. FDA's long-standing interpretation that it has no jurisdiction over cigarettes, absent evidence of the requisite intended use which brings cigarettes within the Act, is well known. That "statutory construction has been 'fully brought to the attention of the public and the Congress,' and the latter has not sought to alter that

interpretation although it has amended the statute in other respects, [thus,] presumably the legislative intent has been correctly discerned." *United States* v. *Rutherford*, 99 S. Ct. 2470, 2476 n.10 (1979).

As stated, Congress has long been aware of the agency's interpretation. See, e.g., Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives, 89th Cong., 2d Sess., on Bills Regulating the Labeling and Advertising of Cigarettes and Relating to Health Problems Associated with Smoking, pp. 13-19 (1964); Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives, 89th Cong., 1st Sess., on H.R. 2248, etc., Cigarette Labeling and Advertising–1965 (1965); Hearings Before the Consumer Subcommittee of the Committee on Commerce, United States Senate, 92d Cong., 2d Sess., on S. 1454, Public Health Cigarette Amendments of 1971, 239-252 (1972). Although bills have been introduced to amend the Act to include cigarettes, these attempts have failed. See, e.g., H.R. 11280, 84th Cong., 2d Sess. (1956) (to establish standards of purity, quality and fitness for human consumption); S. 2554, 85th Cong., 1st Sess. (1957) (label warning requirement); H.R. 592, 85th Cong., 1st Sess. (1957); S. 1682, 88th Cong., 1st Sess. (1963); H.R. 5973, 88th Cong., 1st Sess. (1963). H.R. 2248, 89th Cong., 1st Sess. (1965); H.R. 279, 96th Cong., 1st Sess. (1979). Evidence in the legislative history of those bills indicates that the bills were intended to expand, and not merely to clarify, FDA's jurisdiction under the Act. For example, when Senator Moss introduced S. 1682, he explained that "this amendment simply places smoking products under FDA jurisdiction along with foods, drugs, and cosmetics." 109 Cong. Rec. 10322 (1963).

FDA has, however, occasionally had evidence that cigarettes have been represented as effective for the prevention or treatment of respiratory and other diseases or for weight reduction. FDA has regarded cigarettes which were so represented by manufacturers or vendors as "drugs". See, e.g., *United States* v. *46 Cartons . . . Fairfax Cigarettes*, 113 F. Supp. 336 (D. N.J. 1953); *United States* v. *354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D. N.J. 1959).

An article may be within FDA's jurisdiction if there is objective evidence that the manufacturer or vendor intends that the article is to affect the structure or a function of the body. In determining the intended use of a product, FDA considers the expressions of the person legally responsible for its labeling and the circumstances surrounding its distribution. Petition No. 1 does not contain examples of any representations by the manufacturers or vendors of cigarettes establishing that cigarettes are intended to affect the structure or any function of the body of man.

Petition No. 1 (p. 5) asserts that cigarettes per se affect the structure and functions of the body. However, effects alone do not establish jurisdiction under section 201(h)(3) of the Act. Even assuming the accuracy of the assertions as to the effects of cigarettes, the petition does not establish that these effects are intended.

Evidence of consumer intent in using a product can be relevant in determining the intended use of the product, and we have considered the evidence of consumer intent presented in Petition No. 1. ASH asserts

that consumers use cigarettes with the intent of affecting the structure or functions of their bodies but the petition does not establish this contention. Indeed, petitioners admit (e.g., Petition No. 1, p. 2) that consumers smoke for a variety of reasons.

After a review of all the evidence on Petition No. 1, we conclude that the evidence presented by petitioners fails to establish that cigarettes are intended "to affect the structure or any function of the body" within the meaning of section 201(h)(3) of the Act.

In addition, we have considered whether granting your request to assert jurisdiction over cigarettes as "devices" would require action precluded by another act of Congress, specifically the Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. 1331-1340, as amended (Petition No. 1, pp. 20-30 and Exhibit IX).

In enacting the FCLAA, Congress was aware that FDA does not consider cigarettes, absent evidence of the requisite intended use, to be within FDA's jurisdiction under the Act. See, e.g., Hearings on H.R. 2248, etc., at 193 (1965). In a March 22, 1965, letter to the Chairman of the Senate Committee on Commerce concerning cigarette labeling and advertising, the Secretary of then Department of Health, Education, and Welfare (HEW) Anthony J. Celebrezze recommended that regulatory authority concerning cigarette labeling be vested in HEW. Secretary Celebrezze argued that HEW should be authorized to require statements on the labeling of cigarette packages and to prohibit or regulate the use of statements that might give consumers the misleading impression that a given

cigarette is safer than others. Hearings Before the Committee on Commerce, United States Senate, 89th Cong., 1st Sess., on S. 559 and S. 547, Bills to Regulate Labeling of Cigarettes and For Other Purposes, pp. 22-26 (1965). Secretary Celebrezze recommended that the preferable manner for vesting regulatory responsibility would be by way of amendment to the federal Hazardous Substances Act (FHSA). Rather than providing the regulatory authority recommended by HEW, Congress mandated a specific warning, and preempted the imposition of a requirement of any other statement relating to smoking and health on cigarette packages. Similarly, Congress opted for the requirement of reports to Congress concerning smoking and cigarette labeling, including recommendations for legislation. We believe that the FCLAA, as amended, and its legislative history is strong evidence that Congress did not intend cigarettes as customarily marketed, and absent evidence of the requisite intended use, to be regulated by FDA under the Act.

We are also mindful of the fact that Congress has specifically excluded tobacco or tobacco products from the coverage of other statutes that otherwise might have applied to them. Thus, tobacco or tobacco products were excluded from the definition of "hazardous substance" under the FHSA, 15 U.S.C. 1261(f)(2); from the definition of "consumer product" under the Consumer Product Safety Act, 15 U.S.C. 2052(a)(1)(B); from the definition of "chemical substance" under the Toxic Substances Control Act, 15 U.S.C. 2602(2)(B)(iii); from the definition of "controlled substance" under the Controlled Substances Act, 21 U.S.C. 802(6); and from the definition of "consumer commodity" under the Fair Packaging and Labeling Act, 15 U.S.C. 1459(a)(1).

Those actions are indicative of the policy of Congress to limit the regulatory authority over cigarettes by Federal agencies. This is particularly true of the amendment of the FHSA to specifically exclude tobacco and tobacco products from the definition of "hazardous substance," 15 U.S.C. 1261(f)(2), encated in response to *American Public Health Ass'n* v. *Consumer Product Safety Comm'n*, Civil Action No. 94-1222 (D.D.C. April 23, 1975) (Exhibit IX to Petition No. 1). That case had held that the Consumer Product Safety Commission (CPSC) had jurisdiction to consider the promulgation of a rule banning high tar cigarettes from interstate commerce. S. Rep. No. 94-251, 94th Cong., 2d Sess. 5 (1976). See also the letter from Elmer B. Staats, Comptroller General, to the Hon. Sam J. Ervin, Jr., Chairman, Senate Committee on Government Operations, 120 Cong. Rec. S. 6225, 6227 (daily ed. April 24, 1974), advising that, although the definition of "hazardous substance" might literally include tobacco products, the FCLAA and its amendments "preempt the field of cigarette smoking and its relation to health."

For the above reasons, FDA is denying your request to assert jurisdiction over cigarettes containing nicotine as "devices" under the Act.

II. Attached Cigarette Filters.

Petition No. 2 requests that FDA recognize jurisdiction over attached cigarette filters, which ASH describes as an "integral part of many brands of cigarette" (p. 6), as "devices" under section 201(h)(2) of the Act. For the reasons discussed below, we are denying this request.

ASH asserts that the manufacturers of cigarettes are making implied claims that bring attached filters within the definition of device. Petition No. 2 provides examples of filter cigarette labeling and advertising, all of which include representations as to the level of tar, nicotine, or other constituents of cigarettes or of cigarette smoke. ASH contends (Petition No. 2, p. 3) that ". . . cigarette filters, which are designed and sold to remove tar, nicotine or harmful gases from tobacco smoke fall squarely within th[e] literal language" of the statutory definition of "device". In addition, ASH asserts that "cigarette manufacturers are using a wide variety of filters and each is making express or implied claims that the use of its filter will mitigate, treat or prevent smoking-related diseases by removing the 'tar,' nicotine or gases from the tobacco smoke" (Petition No. 2, p. 14).

In this connection, we have also reviewed the cigarette advertisements presented to the Anesthesiology Device Section of the Respiratory and Nervous System Devices Panel (formerly the Anesthesiology Device Classification Panel). In addition, we have considered the transcript of the Panel's deliberations concerning cigarette filters and the conclusion of the Panel that attached cigarette filters are "devices." We do not agree with the Panel's assessment of advertisements for filtered cigarettes and find that the advertisements presented to the Panel are of the same nature as the filter cigarette advertisements attached to Petition No. 2.

Representations in cigarette labeling or advertising of the nature of those in the record of Petition No. 2 as to the absolute or relative quantity of hazardous

constituents of cigarette smoke or as to the safety of the cigarettes do not make the cigarettes or their filters intended for use in the mitigation, treatment, or prevention of disease.

The representations in the filtered cigarette labeling and advertising in Petition No. 2 are made in the context of long-standing public discussion of potential health hazards of smoking and, in recent years, of warnings which have been statutorily required on cigarette packages. ASH provided in Petition No. 2 as "good examples" (p. 11) of implied claims a series of advertisements (Exhibits H-O) (see also pp. 11-14 and Exhibits P-W). ASH itself admits that the advertisements do not imply that there is a health benefit for which purpose the filter cigarettes should be used, absent the desire to smoke (p. 12; see also Petition No. 1, p. 34).

Where, as here, attached filters are at most represented as making the cigarettes to which they are attached less hazardous to smoke, neither the cigarettes nor the filters are thereby intended for use in the mitigation, treatment, or prevention of disease.

FDA or its employees may have previously responded in a different manner to inquiries about cigarettes. FDA's position concerning representations of the types discussed above for cigarettes with attached filters is set forth herein and any inconsistent prior statements or opinions issued by or on behalf of FDA or any of its employees are hereby rescinded.

ASH asserts that objective evidence other than manufacturers' claims can be material to a deter-

mination of intended use under the statutory definition, and that *National Nutritional Food Ass'n* v. *Food and Drug Administration*, 504 F.2d 761 (2d Cir. 1974), *cert. denied*, 420 U.S. 946 (1975), is authority for this interpretation (Petition No. 2, p. 21). We agree. However, the court there held that the vendor's intent is the crucial element in the statutory definition and that objective evidence sufficient to pierce the manufacturer's subjective claims must be presented (504 F.2d at 789).

As Petition No. 2 also discusses, in *National Nutritional Foods Ass'n* v. *Weinberger*, 512 F.2d 688 (2d Cir. 1975), the court indicated that a finding that the product was used by consumers almost exclusively for therapeutic purposes could support a determination that the product was *intended* for use in the cure, mitigation, prevention, or treatment of disease (512 F.2d at 703). In *National Nutritional Foods Ass'n* v. *Mathews*, 557 F.2d 325 (2d Cir. 1977), the court reiterated that vendor intent in selling a product to the public is the key element in the statutory definition (557 F.2d at 333). Those cases support FDA's position that it is the intent of the manufacturers or vendors that objective evidence must establish and that evidence of consumer use can be one element of objective evidence to be weighed in determining if the intended purpose of a product subjects it to regulation under the Act. ASH has not established that consumers use attached cigarette filters for the prevention, mitigation, or treatment of disease to the extent necessary to allow FDA to impute the requisite intended uses to manufacturers or vendors.

The evidence presented in Petition No. 2 concerning consumer intent regarding attached filters establishes at most that many consumers may regard attached filters as reducing exposure to hazardous constituents of cigarettes and creating a "safer" cigarette. As noted above, this will not bring attached filters within the definition of "device".

Because attached filters are necessarily used with the cigarettes of which they are constituent parts, the intent of consumers in using attached filters is reasonably understood and assessed together with consumer intent with respect to filtered cigarettes. ASH has not asserted that cigarettes with filters are intended to prevent, mitigate, or treat disease. Petition No. 1 expressly disclaims reliance on such an assertion when it discusses *FTC* v. *Liggett & Myers Tobacco Co.*, 180 F. Supp. 573 (S.D.N.Y. 1952), *aff'd*, 203 F.2d 955 (2d Cir. 1953). Petition No. 1 characterizes as "tenuous" the very line of reasoning that Petition No. 2 relies upon in asserting that attached cigarette filters are intended to mitigate, treat, or prevent disease (Petition No. 1, p. 17).

We have also considered ASH's arguments concerning the intent of researchers, and find that the material in Petition No. 2 concerning that intent does not lead to different conclusions than does the evidence of consumer intent regarding attached filters.

For these reasons, FDA is denying your request to assert jurisdiction over attached filters as "devices" under the Act. We believe that congressional consideration of cigarettes included filter cigarettes and, as discussed in Section I, supports our conclusion that

attached filters, as customarily marketed, are not within FDA's jurisdiction.

III. Detached Filters

ASH contends that detached filters, which are purchased separately from cigarettes and "installed by the smoker on the end of the cigarette" (Petition No. 2, p. 6), are subject to FDA's jurisdiction because:

1. Detached filters are advertised as useful in the mitigation, treatment, or prevention of disease (p. 6); or

2. Detached filters are advertised as useful aids in efforts to stop smoking and, therefore, are articles intended to affect the structure or function of the body or to mitigate, treat, or prevent disease (p. 8); or

3. Consumers use detached filters intending to mitigate, treat, or prevent disease (p. 16).

For the reasons stated below, the requests in Petition No. 2 with respect to detached filters are granted in part and denied in part.

We have reviewed the labeling and advertising submitted in Petition No. 2 concerning detached filters to determine whether representations for these products establish that detached filters are intended to be used to mitigate, treat, or prevent disease or to affect the structure or function of the body. We agree that some of that labeling and advertising establishes that manufacturers of certain detached filters, i.e., One Step At A Time, Venturi, and Nu Life Smokers Kit, have made

representations that would bring these products under the device definition and, thus, FDA's jurisdiction.

The labeling and advertising submitted for other detached filters, i.e., Aquafilter and Medico Charcoal Filters, do not establish that these products are intended for a purpose that would bring them within the definition of device.

We would point out that all of the detached filters for which labeling and advertising were submitted in Petition No. 2 are intended to reduce the amount of tar, nicotine, or gases inhaled by the smoker or to aid the smoker to reduce or stop smoking. This does not establish manufacturer intent to mitigate, treat, or prevent disease, or to affect the structure or function of the body. As noted in Section II, we do not agree with the assertion in Petition No. 2 that "cigarette filters which are designed and sold to remove tar, nicotine or harmful gases from tobacco smoke" fall squarely within the literal definition of "device." Manufacturers of detached filters which are intended to remove tar, nicotine, and gases or to aid the smoker to reduce or stop smoking may be responding to consumer demand for a low tar, low nicotine, low gas cigarette, or a stop smoking aid to enable them to reduce the costs of smoking or eliminate the odor associated with smoking, etc. Only if detached filters intended for these purposes are coupled with other evidence that, when viewed together, establish the requisite intended use, will the products come within FDA's jurisdiction.

As noted in Section II, a claim of general or comparative safety, without more, will not usually cause a product to be subject to the Act. Many products are

designed and sold to be used to reduce the exposure of humans to hazardous substances. For example, catalytic convertors and lead-free gasoline for use with automobiles are designed to reduce the exposure of humans to lead and hazardous by-products of gasoline combustion. These products, however, are not deemed to be within the Agency's jurisdiction. The determination that a product is properly regulated under the Act is not left to FDA's unbridled discretion but must be in accordance with the statutory definition. *United States* v. *62 Cases of Jam*, 340 U.S. 593 (1950).

ASH's contention that consumer use of (or researchers' intent with respect to) detached filters brings these products within FDA's jurisdiction is identical to petitioner's discussion of attached filters. Our position is the same as discussed under Section II of this letter, as supplemented by our discussion above of evidence of intended use.

Therefore, Petition No. 2 has not provided evidence establishing FDA's jurisdiction over all detached filters. As stated above, we have concluded that FDA has jurisdiction over particular detached filters for which the evidence of the requisite intended use has been shown in Petition No. 2. The evidence in Petition No. 2 has also established that detached filters have been marketed with labeling and advertising which do not provide evidence of the requisite intended use.

FDA may have previously responded to inquiries regarding detached cigarette filters intended to aid the smoker to reduce or stop smoking. As noted under Section II with respect to attached filters, this response sets forth FDA's position and rescinds any earlier

correspondence or opinions concerning detached filters that may be in conflict.

IV. Rulemaking

ASH has requested that FDA commence rulemaking proceedings to establish the means by which FDA should exercise its jurisdiction over cigarettes and attached and detached filters as medical devices. In the FEDERAL REGISTER of November 2, 1979, FDA stated that it was not issuing a proposed regulation to classify cigarette filters pending action on ASH's petition (44 FR 63292 at 63299). ASH's request to commence rulemaking is granted in part and denied in part.

Insofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction under section 201(h) of the Act. Therefore, no rulemaking is permissible as a matter of law.

Insofar as rulemaking would relate to detached filters, we have concluded that FDA has jurisdiction under section 201(h) of the Act over some, but not all, detached filters. We are granting your request that FDA institute rulemaking with respect to those detached filters over which FDA has jurisdiction.

In accordance with 21 CFR Part 860, FDA will propose to classify detached filters that are medical devices. FDA currently does not intend to institute other rulemaking proceedings specifically for these detached filters. However, rulemaking that FDA institutes with respect to other articles may also be applicable to detached filters that are devices.

Sincerely yours,

/s/ [ILLEGIBLE]
For JERE E. GOYAN
Commissioner of Food and Drugs